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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,830	02/08/2002	Dong Feng Chen	ERM-105.01	2287
25181	7590	10/14/2004	EXAMINER	
FOLEY HOAG, LLP			CHERNYSHEV, OLGA N	
PATENT GROUP, WORLD TRADE CENTER WEST			ART UNIT	
155 SEAPORT BLVD			PAPER NUMBER	
BOSTON, MA 02110			1646	

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,830

Applicant(s)

CHEN ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 10-21, 25, 26 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9, 22-24 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

1. Claims 1-26 and 31-37 are pending in the instant application.

Claims 1-6, 10-21, 25-26, 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 7-9, 22-24 and 34-37 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on July 22, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

5. Claims 7-9, 22-23 and 34-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Chen D. F. et al. in view of Chen R.-W. et al. for those reasons of record in section 6 of Paper mailed on April 21, 2004.

Applicant traverses the rejection on the premises that "at the time the priority application was filed, it was not known what levels of BCL-2 were necessary to promote axonal growth. Even if Chen R.W. et al. were teaching that lithium induces Bcl-2 expression, there were no evidence that lithium would stimulate Bcl-2 expression to levels and for time sufficient to

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promote axonal growth” (Page 5, first paragraph of the Response). Applicant further states that “it was not until the inventors tested out the effect of lithium on axonal growth, that they found that lithium did promote axonal growth” (third paragraph). These arguments have been fully considered but are not persuasive for the following reasons.

Claims 7-9, 22-23 and 34-37 are directed to a method for stimulating axon growth of a neural cell by contacting the cell with an amount of lithium or salt thereof sufficient to stimulate axon growth and confirming that axonal growth occurred. Chen D. F. et al. experiments were done “[t]o determine whether *bcl-2* is required for the growth of retinal axons” (page 436, first column). At page 436, second column, Chen D. F. et al. state “we can conclude that *bcl-2* is central to the regulation of the intrinsic genetic program for retinal axonal growth”, and, further at page 437, first column, “*bcl-2* promotes retinal axon regeneration *in vivo*”. Thus, in 1997, when the article by Chen D. F. et al. was published, it was known that “the proto-oncogene *bcl-2* plays a key role in [... promotion of] the growth and regeneration of retinal neurons” (see the abstract) and it was also suggested that these data “provide[s] a basis for the design of new therapeutic strategies for treatment of brain and spinal injuries, as well as many neurodegenerative diseases” (middle at first column at page 438). Chen D. F. et al. used transgenic animals for their experimental research and did not use any factors, such as lithium, that would specifically affect *bcl-2* expression. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to use drugs that specifically affect *bcl-2* expression to stimulate axonal growth and regeneration, such as lithium, which when used in concentrations 0.5-5 mM “remarkably increased” Bcl-2 mRNA levels in cerebral granule cells, according to Chen R.-W. et al. published in 1999. The motivation reason to do this would be

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supported by combining the knowledge clearly provided by two articles as well as straight forward logic that in order to stimulate axonal growth, *bcl-2* levels must be elevated (Chen D. F. et al.) and lithium is the factor to elevate *bcl-2 levels* (Chen R.-W. et al.).

6. Claim 24 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al in view of Chen R.-W. et al. for reasons of record in section 7 of Paper mailed on April 21, 2004.

Applicant submits that “the Zhang et al. and Chen R.-W. et al. do not teach or suggest all the claim limitations. Because these references are limited to neurite growth, they do not teach or suggest that lithium would stimulate the growth of axon. One having ordinary skill in the art would understand that “neurite” refers to the generic neural cell structures having the potential of forming either axons or dendrites” (third paragraph at page 7 of the Response). This argument has been fully considered but was not found persuasive because, according to the knowledge in the art, neurites are neuronal processes represented by axons or dendrites. Because reference of Zhang et al. discloses that overexpression of Bcl2 cDNA induced extensive neurite outgrowth in Paju tumor cells, one skilled in the art would readily understand that, first, it is difficult to differentiate axons from dendrites in cells of neuronal origin in culture, and, second, that there is no information presented in the article that would specifically indicate that only dendrites, which the exclusion of axons, were stimulated by Bcl2 overexpression, absent evidence to the contrary.

Conclusion

7. No claim is allowed.

8. This application contains claims 1-6, 10-21, 25-26, 31-33, drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include

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cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

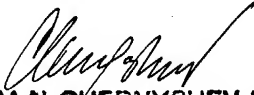
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published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER